Transonic Systems Inc.
The Flow Measurement Specialists

510(k) SUMMARY
Summary of Safety & Effectiveness

Submitter's Name & Address:	Transonic Systems, Inc. 34 Dutch Mill Road Ithaca, NY 14850
Contact Person & Telephone:	David Klementowski 607-257-5300
Date Summary Prepared:	September 9, 2011
Device Name:	Classification Name – Flowmeter, Blood, Cardiovascular Common/Usual Name - Blood Flowmeter Proprietary Name - AureFlo Monitoring System
Predicate Device:	K040228 Medi-Stim VeriQ System

Device Description

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic Systems AureFlo Monitoring System. The device is a versatile monitoring system to continuously measure, display, record and document absolute volume flow and other derived parameters. It is used during surgery with Transonic Flowprobes to measure and display blood flow in vessels. It can also be used with Sterile Tubing Flowsensors to measure and display flow of fluids through tubing circuits. *AureFlo's* flexible integrated system can be set up in a variety of configurations. A stand-alone HT300-Series flowmeter can be upgraded to work with *FlowTrace®* software. The system can also be set up on any operating room cart with an optional monitor stand.

The display panel is an Intel® Pentium M® CPU touch-screen computer/monitor with Microsoft Windows XP®. The computer/monitor's manual can be accessed by selecting "Help" on the Windows Start Screen. *FlowTrace®* Software works exclusively with HT300-Series-FT Flowmeters to provide a real-time waveform display of volume flow, mean flow and Pulsatile Index (PI). During CABG surgery, connection with an ECG signal allows for an on-screen ECG display, diastolic/systolic shading of coronary graft waveforms and calculation of a D/S (diastolic/systolic) Ratio.

Intended Use

The AureFlo Monitor is intended for use with Transonic Systems' HT300-Series-FT Surgical Flowmeters. These Flowmeters are intended for use with adult and pediatric patients for measurement of blood or liquid volume flow with Transonic perivascular Flowprobes on major and peripheral arteries, veins and ducts; on non-aerated synthetic vessel grafts; where surgery is medically indicated; intraoperatively, rather than in chronic implant; at intraoperative sites which admit and retain ultrasonic couplant; with minimal vessel manipulation or constriction (to avoid vessel spasm); where application does not unnecessarily lengthen surgical procedure. Measurement of blood or perfusate volume flow with sterile tubing Flowsensors on flexible tubing specific to the flowsensor (never on arteries, veins) and for non-aerated media which are transparent to ultrasound.

Technological Characteristics Compared to Predicate Device

Characteristic	Transonic Systems AureFlo Monitoring System	Medi-Stim VeriQ System
Flow measurements		
> Technology	Ultrasonic Transit-time	Ultrasonic Transit-time, PW Doppler
> No. of channels	1 or 2	1, 2 or 4
> Measured parameters	Mean and pulsatile flow values	
> Simulated Doppler sound	Yes	
> Type of probes	Perivascular, cardiac output and tubing measurements	Perivascular, cardiac output and tubing measurements
User Interface		
> Flow line zero calibration	Automatic (EEPROM)	Automatic (EEPROM)
> Controls	Touch screen	Touch screen
> Read-out	15" LCD display	19" LCD display
> Documentation	Patient database (hard disk), print-out or pdf output via external memory	Patient database (hard disk), print-out or HTML output via external memory
Technology Platform		
> Hardware	Proprietary analog transit time front end with post-processing circuitry	Pentium microprocessor Proprietary digital transit time front end
> Software	Windows XP	Windows XP

Conclusions and Safe & Effectiveness

The AureFlo Monitoring System is deemed to be safe and effective based on the safety testing completed by TUV Rheinland of North America, Inc., in accordance with the IEC 60601-1 Medical Electrical Equipment standard. This system also tested to and found to be in compliance for electromagnetic compatibility in accordance with the CISPR 11 standard.

In addition, bench testing was conducted by Transonic Systems Inc. and the validation report can be found in Section 18 of this 510(k) submission. Prior to shipment, the finished product will be tested and must meet all required release specifications before distribution. The array of testing required for release includes, but are not limited to; physical testing and visual examination (in-process and finished product). The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures that ensure the product's performance parameters conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed, and revised in accordance with document control cGMP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 21 2011

Transsonic Systems, Inc.
c/o Mr. David Klementowski
VP, Regulatory Affairs and Quality
34 Dutch Mill Road
Ithaca, NY 14850

Re: K112657
Trade/Device Name: Transonic Systems AureFlo Monitoring System
Regulation Number: 21 CFR 870.2100
Regulation Name: Flowmeter, Blood, Cardiovascular
Regulatory Class: Class II
Product Code: DPW
Dated: December 7, 2011
Received: December 8, 2011

Dear Mr. Klementowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112657

Indications for Use

510(k) Number (if known):

Device Name: Transonic Systems AureFlo Monitoring System

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Nilsen for Bram Zuckerman
Director DCD

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112657